Remarks

Claims 1, 19-21, 30-34, 36, and 39-48 are pending in the application. Claims 22, 24 and 27-29 have been cancelled by the present amendment, without prejudice to the filing of one or more continuing applications.. Claims 1, 19-21, 30-33 and 42-48 have been withdrawn from consideration pursuant to a restriction requirement. Claims 34, 36 and 39-41 are under consideration and stand rejected. Reconsideration is requested in view of the above changes and the following remarks.

Acknowledgement of Examiner Interview

Applicant thanks Examiner Angela Scott and for the courtesy extended during the telephonic interview of March 4, 2011 with the undersigned attorney. Claims 22 and 34 were discussed. The prior art of record was discussed – Shalaby (US 2004/0133237). The arguments presented by applicant's attorney during the interview were as substantially recited below. The sketches contained in the argument below were presented during the interview. No agreement as to allowability was reached. However Examiner Scott agreed to consider a response after final rejection presenting the arguments substantially as set forth below.

The amendment presented herein, cancelling claims, may be entered notwithstanding the finality of the pending office action (37 C.F.R. 1.116(b)(1) "An amendment may be made cancelling claims…").

Response to 35 USC §102 Rejection of Claims 22, 24 and 27-29

Claims 22, 24 and 27-29 have been rejected as being allegedly anticipated by Shalaby. The rejection is moot in view of the cancellation of these claims.

Response to 35 USC §102 Rejection of Claims 34, 36 and 39-41

Claims 34, 36 and 39-41 have been rejected as being allegedly anticipated by Shalaby. The rejection alleges that Shalaby teaches an absorbable medical device, such as a suture, that is irradiated with an electron beam. The rejection alleges that since the outer surface of the objects irradiated by Shalaby receives more radiation, the outer surface would have a lower molecular

weight than the inner core of the object.

Even assuming *arguendo* that a gradient could be created using the teachings of Shalaby, which applicant contends would not happen, such a gradient would not run from the *entire* outer surface to the core, as is required by the present claims. It is inherent from Shalaby that any gradient would run from the outer surface of the article proximate to the source of radiation, to the outer surface distal to the source of radiation. There is no disclosure in Shalaby of moving the surface of the suture relative to the radiation source. It is clear, therefore, that the radiation would be applied to the suture from a fixed angle. This could not result in an article in which the *entire* outer surface of the article has been irradiated to a higher level (and thus having its mass distribution reduced/bioabsorbability increased), as the core would actually receive a higher radiation dose than the distal surface. Such a gradient would not be within the ambit of the present clams. Furthermore, such a gradient would not be desirable as it would not allow for the controlled bioabsorption of the article from the outer surface toward the core.

Figure 1, below, shows conventional electron beam sterilization, as would be allegedly employed by Shalaby. The object to be sterilized is moved on a conveyor belt through an electron beam with a suitable penetration energy in relation to the device dimensions and material such that a suitable dose of radiation, which can penetrate the device in a short time.

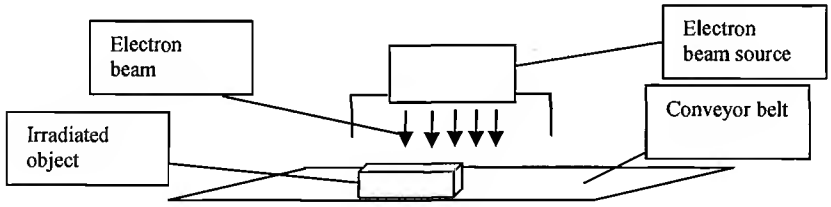

Figure 1

There is no disclosure in Shalaby of moving the surface of the object relative to an electron beam source such that an electron beam is provided to all surfaces of the object. Any molecular weight gradient created by Shalaby would run from the outer surface of the object proximate to the source of radiation (region of highest radiation), to the outer surface distal to the source of radiation (region of lowest radiation), as illustrated by Fig. 2:

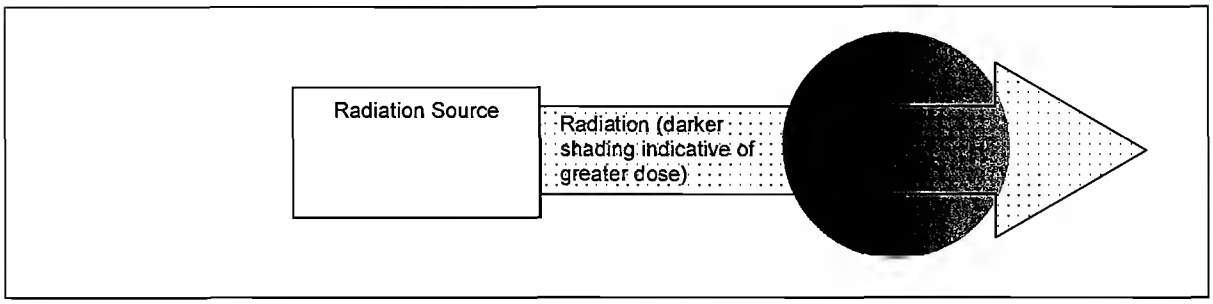

Figure 2

Claim 34 requires that "the average molecular weight at the core is greater than the average molecular weight at the *entire outer surface*" of the irradiated object. Shalaby would only provide the result in Fig. 2, wherein the shading is inversely proportional to the molecular weight. Clearly, it cannot be said that the average molecular weight would be greater at the core than the *entire* surface. The surface distal to the electron beam source would not have a molecular weight lower than the core, as shown in Fig. 2.

The radiation dose as provided to an object according to the present invention is represented by Figure 3. The shading, representing the radiation dose, is inversely proportional to the average molecular weight. All regions of the surface have a molecular weight that is lower that the molecular weight at the core .

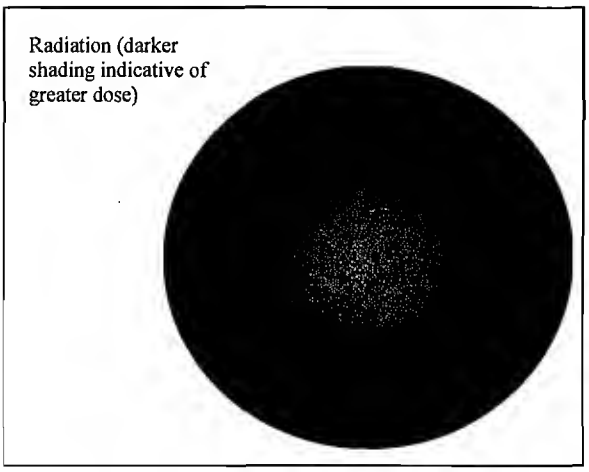

Figure 3

Accordingly, it has been shown that the articles (sutures and adhesive) of Shalaby do not inherently comprise a gradient in the orientation as required by the present claims.

The bioabsorbable, implantable substrate of claim 34 is novel and nonobvious over Shalaby. Claim 34, and its dependent claims 36 and 39-41 are allowable for Shalaby.

Conclusion

The claims remaining in the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

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